



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request; Post-Award Reporting

Requirements Including Research Performance Progress Report Collection (Office of the Director)

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301-435-0941 or Email your request, including your address to ProjectClearanceBranch@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was

previously published in the Federal Register on April 12, 2021, pages 18994-18995 (86 FR 18994) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Office of the Director (OD) Office of Policy and Extramural Research Administration (OPERA), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Public Health Service (PHS) Post-award Reporting Requirements Including Research Performance Progress Report Collection, Revision, OMB 0925–0002, Expiration Date 2/28/2023, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: This collection is being revised to omit the Inclusion Enrollment Report form, which is being converted to a Common form to include the Department of Defense (DoD). The Inclusion Enrollment Report is used for all applications involving NIH-defined clinical research. This form is used to report both planned and cumulative (or actual) enrollment, and describes the sex/gender, race, and ethnicity of the study participants. Starting in January 2022, NIH will require will applicants and recipients to provide their Unique Entity Identifier (UEI) instead of the Data Universal Number System (DUNS) number. Also, the application forms will be updated to align with the Grants.gov updated Country and State lists. NIH also anticipates adding an optional field to the end of our forms and applications to get a more

accurate assessment of the time it takes our applicants to complete the various forms and applications. The RPPR is required to be used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR required the maintenance of dual reporting processes for a period of time. Continued use of the PHS Non-competing Continuation Progress Report (PHS 2590), exists for a small group of grantees. This collection also includes other PHS post-award reporting requirements: PHS 416–7 NRSA Termination Notice, PHS 2271 Statement of Appointment, 6031–1 NRSA Annual Payback Activities Certification, HHS 568 Final Invention Statement and Certification, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. The PHS 416–7, 2271, and 6031–1 is used by NRSA recipients to activate, terminate, and provide for payback of a NRSA. Closeout of an award requires a Final Invention Statement (HHS 568) and Final Progress Report. iEdison allows grantees and Federal agencies to meet statutory requirements for reporting inventions and patents. The PHS 3734 serves as the official record of grantee relinquishment of a PHS award when an award is transferred from one grantee institution to another. Pre-award reporting requirements are simultaneously consolidated under 0925–0001 and the changes to the collection here are related. Clinical trials are complex and challenging research activities. Oversight systems and tools are critical for NIH to ensure participant safety, data integrity, and accountability of the use of public funds. NIH has been engaged in a multi-year effort to examine how clinical trials are supported and the level of oversight needed. The collection of more structured information in the PHS applications and pre-award reporting requirements as well as continued monitoring and update during the post-award reporting requirements will facilitate NIH’s oversight of clinical trials. In addition, some of the data reported in the

RPPR will ultimately be accessible to investigators to update certain sections of forms when registering or reporting their trials with ClinicalTrials.gov. *Frequency of response:* Applicants may submit applications for published receipt dates. For NRSA awards, fellowships are activated, and trainees appointed.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 532,249.

Estimated Annualized Burden Hours

Information Collection Forms	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
REPORTING				
PHS 416-7	12,580	1	30/60	6,290
PHS 6031-1	1,778	1	20/60	593
PHS 568	11,180	1	5/60	932
iEdison	5,697	1	15/60	1,424
PHS 2271	22,035	1	15/60	5,509
PHS 2590	243	1	18	4,374
RPPR – Core Data	32,098	1	8	256,784
Biosketch (Part of RPPR)	2,544	1	2	5,088
Data Tables (Part of RPPR)	758	1	4	3,032
Trainee Diversity Report (Part of RPPR)	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes inclusion enrollment report)	6,420	1	4	25,680
Publication Reporting	97,023	3	5/60	24,256

Final RPPR – Core Data	18,000	1	10	180,000
Data Tables (Part of Final RPPR)	758	1	4	3,032
Trainee Diversity Report (Part of Final RPPR)	480	1	15/60	120
PHS Human Subjects and Clinical Trial Information (Part of RPPR, includes inclusion enrollment report))	3,600	1	4	14,400
PHS 374	479	1	30/60	240
Reporting Burden Total				531,874
RECORDKEEPING				
SBIR/STTR Life Cycle Certification	1,500	1	15/60	375
Grand Total	217,653	411,699		532,249

Dated: July 30, 2021.

Lawrence A. Tabak,

Principal Deputy Director,

National Institutes of Health.